

## Laboratory Medicine: Completing Request Forms and Labelling Samples Policy

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Target audience:	All staff who fill in request forms and label samples for work to be undertaken in Laboratory Medicine
Relevant Regulations and Standards	ISO 15189; 2012 Blood Safety and Quality Regulations (2005) HSE Regulations NHSLA 5.6/5.7
Links to Organisational/Service Objectives, business plans or strategies	Improve Quality & Safety
<b>Executive Summary</b>	
This policy describes the requirements for completing request forms and labelling samples to facilitate correct identification of patients and maximise the useful information available in the report.	

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## Version History Log

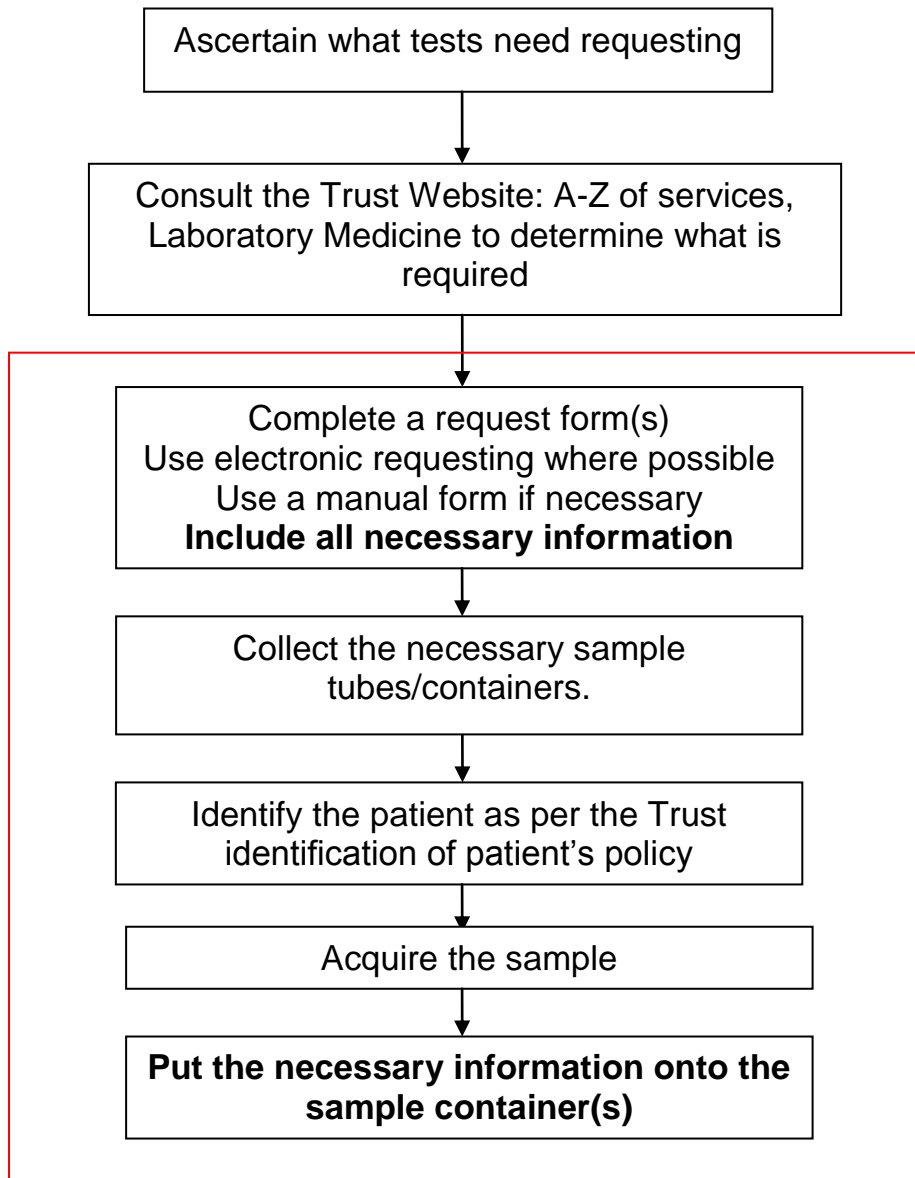
This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Approved	Version Author	Status & location	Details of significant changes
01	14/03/2005	Graeme Claxton	Obsolete	First Publication
02	08/03/2007	Graeme Claxton	Obsolete	Amendments to appendix1 regarding the use of Nuffield's unique patient numbers and the use by Capio of NHS numbers for transfusion samples.
03	28/04/2009	Graeme Claxton	Obsolete	Change to Trust Policy Format
04	09/09/2011	Graeme Claxton	Obsolete	3.1.6 Handwritten additions to Ordercomms requests not acceptable
05	19/05/14	Elizabeth Fox	Active	Updated to new Trust format. Reference to ISO 15189; 2012 in Introduction scope and practice. Removal of 3.2.4 Microbiology special conditions no longer apply.
06				Rewrite for clarity – location deemed as essential.

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## Process flowchart



# 1 Introduction & Scope

Clinical Governance demands that at the time of request a sample must be uniquely labelled and uniquely associated with a test request. The information which appears on a specimen and on the accompanying request form MUST match and fulfil the minimum criteria set out by accreditation bodies for Laboratory Medicine. The location of the patient and the identity of the requestor must be accurately stated and relevant clinical details supplied as appropriate for interpretation and reporting of results.

This policy sets out the requirements for correct sample and request form labelling for all requests received by Laboratory Medicine in a manner that provides an unequivocal link with the patients from whom they are collected.

In the interests of patient safety and diagnostic management, both request form and samples, must contain an adequate amount of information. Any sample which does not contain the essential labelling requirements may be rejected, as this may put patients at risk. No patient should suffer an adverse outcome, or delay in treatment, due to the mislabelling of samples or request forms.

Laboratory Medicine is accredited by the UK accreditation body, UKAS, against the standard BS EN ISO 15189: 2012: Medical laboratories – Requirements for quality and competence which defines the requirements for the completion of request forms and sample labelling in the secondary sub-clause 5.4.4 Primary sample collection and handling.

Further requirements are set in the MHRA standards for GMP/GLP to meet the EU directive / Blood Safety and Quality Regulations (2005) and the risk standards published by NHSLA for CNST requirements.

This policy is aimed at all staff involved in arranging/initiating requests and/or acquiring samples for sending to Laboratory Medicine and must be used in conjunction with Trust identification of patients policy.

## 2 Definitions / Terms used in policy

**Sample:** any body fluid or piece of tissue that requires testing by Laboratory Medicine.

**Unique Identifier:** An identifier that must be unique to each patient, normally their NHS number.

**High Risk Samples:** Samples from patients with possible or actual category 3 or higher infections; TB, HIV, Hepatitis B, Hepatitis C, vCJD, those with unexplained jaundice, those with unexplained pyrexia (returning from foreign travel) or IV drug abusers.

## 3 Policy Statement

### 3.1 General

- The responsibility for requesting a laboratory service/test lies with the patient's medical team. Thus, it is the responsibility of the requestor to ensure that samples are correctly labelled and request forms completed to the agreed standard and fulfil the minimum criteria set out by accreditation bodies for Laboratory Medicine stated in this policy.
- At the point where the patient is identified prior to taking the sample, the York Trust patient identification policy must be used.
- Before accepting a clinical specimen, laboratory staff must ensure the minimum criteria for sample identification are met as stated in this policy. Departmental Standard Operating Procedures (SOP's) are aligned to this policy.
- Compliance will be monitored in the reception areas of Laboratory Medicine but only obvious anomalies can be identified in this way. Correctly filled in request forms and labelled samples where the wrong patient has been bled could cause an adverse outcome for either of the two patients involved and could lead to a claim or other action questioning fitness to practice.

### 3.2 High Risk Samples

Any request on a patient who comes under the category of 'high risk', as defined above, must include indication of this on the request form.

The HSE advise the provision of sufficient information on Specimen Request forms to staff in Clinical Diagnostic Laboratories to enable them to apply the correct safety measures to control the risk. The lack of sufficient relevant clinical details provided on specimen request forms can result in samples being handled at the wrong biological containment level with resulting increased risk of infection to laboratory staff.

### 3.2 Order Comms

- For samples requested in order comms, requestors must ensure all samples are labelled with the correct barcodes and the barcodes must be placed in the correct orientation.

### 3.3 Labelling Criteria (Not Blood Transfusion)

Identifiers must be correctly spelt and complete, i.e. initials are insufficient, as is an age of a patient or just a year of birth. Details should be written legibly, preferably in CAPITALS.

All requests for **cervical cytology** should be accompanied by the special (HMR 101/5) forms and all details must be completed with the full patient address, NHS number, and sender details along with the smear takers unique LBC smear taker code.



**Details in bold are also deemed essential**

**Sample Labelling (Not Blood Transfusion)**

- **Patient's full name (or unique coded identifier as in GUM patients)**
- **Date of Birth**
- **NHS, CHI or Health and Care number**
- Sample type (s) and anatomical site (s) (essential for Microbiology and Histology)
- Date & Time Taken
- Patient's location/source

**Request form Labelling (Not Blood Transfusion)**

- **Patient's full name (or unique coded identifier as in GUM patients)**
- **Date of Birth**
- **NHS, CHI or Health and Care number**
- **Date & time taken (which may be essential for Biochemistry specimens)**
- **Investigation (s) required**
- **Type and site of specimen (essential for Microbiology and Histology)**
- **High Risk Status**
- **Patient's location and destination of report**
- **Patient's consultant, GP or name of requesting practitioner** (contact number, bleep or extension).

The name of the requestor, who should normally be medical, must be provided to satisfy requirements for consent to test. This is particularly important for sensitive tests such as HIV, syphilis, chlamydia etc.

- Patient's gender and if pregnant
- Patients address
- Clinical information including relevant medication (which is sometimes essential e.g. Drug History (dose & time of last dose for drug assays), Antibiotic History (vital as part of microbiology request))

**The NHS, CHI or Health and Care number is essential on all samples.** Use of the NHS number, CHI or Health and Care number on paper and electronic patient records is a mandatory requirement included within the NHS Operating Framework 2008/9.

The Laboratory Medicine computer system uses the NHS number as the primary patient identifier so that all data can be linked and patients identified.

1. Everyone registered with the NHS in England and Wales has their own unique NHS Number made up of 10 digits shown in a 3-3-4 format.
2. The Health and Care Number was introduced for the use and benefit of patients and clients resident within Northern Ireland. This number will be used, from birth, for life for receipt of Health and Social Services in Northern Ireland. The Health and Care Number is a 10 digit number randomly selected and allocated to everyone in Northern Ireland. The first two characters of the Health and Care Number must always lie within the range 32 - 39.
3. Everyone registered with a Scottish GP practice has their own unique ten-digit number Community Health Index (CHI) number.

### **3.4 Blood Transfusion Labelling Criteria**

***In the case of Blood Transfusion requests, special conditions apply please refer to the Trust Blood and Blood Component Policy for full details***

The importance of correct patient identification, sample labelling, documentation and record keeping cannot be overstated since most deaths associated with blood transfusion are a result of clerical errors.

A request to the Blood Transfusion laboratory is represented by the provision of information sufficient to satisfy minimum requirements for identification and documentation.

The patient ID must be unique and there must be an auditable link between each stage of the procedure, from sample collection to final reporting/issuing of compatible blood.

Blood Samples must be taken and labelled from one patient at a time.

The sample tube must be labelled immediately after the blood has been added by the person taking the sample. **This should be done at the (bed)side of the patient.** An addressograph or ICE/order comm label must not be used on the sample tube; if used the sample will not be processed by the transfusion department.

### **Sample Labelling**

#### **For Crossmatch or Group and Save Samples.**

It is essential that the sample contain the following correct minimum patient identification. These must be hand written on to the specimen tube.

- (i) Surname (correctly spelt);
- (ii) Full first name (correctly spelt and not initials);
- (iii) Date of birth (not age or year of birth);
- (iv) A unique numeric identifier, for example the NHS number.
- (v) Signature of the individual who has drawn the sample
- (vi) Date & Time sample taken

### **Blood Transfusion Request Form Labelling**

The request form must contain the same patient identifiers as the specimen together with further essential information; Location, gender of the patient, Consultant and/or GP, clinical details, number or volume and type of components required, and any other specific requirements relating to the request or patient e.g. irradiated products required.

#### **Antenatal Requests**

In addition to the above, please include the following essential information; patient address, location, GP and/or consultant and E.D.D.

### **3.5 The unidentified patient**

In the case of an unconscious, unknown patient, 'unknown male/female' should be used on the wrist ID band along with a unique identifier (not ED number). This number will be used as the identification number until the patient is formally identified.

In the event of a major incident the 10 digit MAJAX number (or equivalent) must be used in place of an NHS or hospital number.

The surname must be given as "unknown" and the gender of the patient entered in the forename box of the form.

Extreme care should be taken in this situation and attempts must be made to identify the patient at the earliest opportunity.

### **3.6 Sample Rejection**

Laboratory Medicine will make every effort to ensure that every specimen is processed correctly and that no vital specimen is lost but, in the event of doubt as to the integrity of the information provided or the source of a specimen, the laboratory reserves the right to refuse to process that request.

Specimens will be accepted for analysis provided:

- Samples are correctly labelled and request forms are completed to the agreed standard and fulfil the minimum criteria set out by accreditation bodies for Laboratory Medicine as stated in this policy to provide an unequivocal link with the patients from whom they have been collected.
- The specimen is appropriate (i.e. correct blood tube, expiry date etc.)
- The investigation required is clearly indicated on the request form.
- The patient details have not been changed on the specimen container.
- The specimen is of acceptable integrity.

If samples or request forms are not labelled with the minimum criteria they may be rejected or the request may be returned to the sender (In these circumstances it will be even more difficult to activate the request if the identity of the sender is not provided).

Laboratory staff MUST not amend details on the sample.

Any sample that is rejected will have a report issued with an appropriate standard comment indicating any deficiencies.

Exceptions may be made in the case of unrepeatable samples listed by department below in [section 3.7](#).

### **3.7 Unrepeatable Samples**

**Biochemistry:** Un-named samples of CSF may be retained and the requesting clinician asked to attend the laboratory to label the specimen.

**Haematology:** For bone marrow aspirates and slides the requesting clinician will be asked to come to the laboratory to complete the details.

**Microbiology:** Blood cultures, CSF, operative samples and other precious specimens that, in the opinion of the Consultant Microbiologist, would be difficult to replace: the requesting clinician may be asked to attend the laboratory to complete the details. The decision to reject samples in Microbiology rests with the Consultant Microbiologist as many samples are unrepeatable after patients have started antibiotic therapy. The Consultant Microbiologist will liaise with clinical colleagues and satisfy themselves as to the degree of doubt concerning identification of a patient and their sample.

**Cytology:** All unlabelled cervical cytology smear liquid based cytology vials will be returned with a covering letter requesting that the smear be repeated. The same process is followed for easily repeated non-gynae samples. Where non-gynae samples are not easily repeated, samples will only be accepted at the discretion of the Histopathologist on duty at the time.

**Histopathology:** Due to the nature of specimens sent to Histopathology, it is not possible to request 'repeat' samples. It is

therefore imperative that all patient identification information is present on both request form and sample. However, should specimens arrive unlabelled, the requesting clinician, or a delegated representative, will be asked to come to the laboratory to complete the details. In the event that a sample has been sent from an off-site source, (e.g. General Practice), the requesting doctor must send written, signed, verification of patient ID.

**In extreme cases** where there constitutes a greater risk to the patient for clinical reasons a Consultant Level Clinician of the relevant department may authorise variation to this policy. In these circumstances, the **requesting clinician must** give written agreement to accept full responsibility for all potential outcomes and liability claims prior to the release of any results or interpretive comments. The report will show a clear disclaimer detailing the shortcomings of the sample and/or request and alerting the requesting practitioner to take responsibility for the results, and for any action taken as a result of the report.

**No deviations will be permitted in relation to blood transfusion requests.**

In all cases of the exceptions, a DATIX form will be completed and submitted to record the incident.

## **4 Impact upon Individuals with Protected Characteristics**

The document author has reviewed this document in conjunction with the Trust's Equality and Diversity Facilitator and has judged that there will be no negative impact on any of the groups of individuals with protected characteristics.

## **5 Accountability**

Operational implementation, delivery and monitoring of the policy reside with:-

- The person completing the request form or label to ensure that sufficient information is provided and that it is correct. The onus is not on the laboratory to make assumptions about

the origins or nature of specimens or the accuracy of any given details.

However there are a number of key responsibilities placed on individuals within the organisation to ensure the effective implementation of this policy:-

- The Clinical Development Team will disseminate the venepuncture good practice points of positive patient identification, accurate sample labelling, and sample integrity through the training framework of theoretical e-learning, practical training, supervised practice, assessment of competence, and supporting resource materials.
- Monitoring of the policy will be conducted by Laboratory Medicine. Deviations from the policy are recorded as DATIX which are reviewed at departmental governance and management meetings.

## **Appendix**

### **Appendix 1: Policy Management**

#### **1 Consultation, Quality Assurance and Approval Process**

##### **Consultation Process**

The Trust will involve stakeholders and service users in the development of its policies.

Consultation has taken place with the following stakeholders:

- Clinical Development Team

##### **Quality Assurance Process**

The author has consulted with the following to ensure that the document is robust and accurate:-

- Laboratory Medicine Clinical Governance Committee and Directorate Management Team

The policy has also been proof read and the review checklist completed by the Policy Manager prior to being submitted for approval.

##### **Approval Process**

The approval process for this policy complies with that detailed in section 6.3 of the Policy Guidance.

The approving body is the Laboratory Medicine Clinical Governance Committee.

#### **2 Review and Revision Arrangements**

The Laboratory Medicine Quality Manager will be responsible for review of this policy in line with the timeline detailed on the cover sheet.



Subsequent reviews of this policy will continue to require the approval of the Laboratory Medicine Clinical Governance Committee.

### **3 Dissemination and Implementation**

Within laboratory Medicine this policy will be kept in documentary control on the directorate's Q-Pulse.

This policy will also be stored on Staffroom, in the policies and procedures section and will be stored both in an alphabetical list as well as being accessible through the portal's search facility and by group. The register of policies will be maintained by the Healthcare Governance Directorate.

This policy will also be stored on the Trust Website, A – Z of Services, Laboratory Medicine. The Laboratory Medicine area of the Website will be maintained by the Quality Manager, Laboratory Medicine.

If members of staff want to print off a copy of a policy they should always do this using the version obtainable from Staffroom but must be aware that these are only valid on the day of printing and they must refer to the intranet for the latest version. Hard copies must not be stored for local use as this undermines the effectiveness of an intranet based system.

### **4 Register/Library of Policies/Archiving Arrangements/ Retrieval of Archived Policies**

On review of this policy, archived copies of previous versions will be automatically held on the version history section of each policy document on Q-Pulse. The Healthcare Governance Directorate will retain archived copies of previous versions made available to them. Policy Authors are requested to ensure that the Policy Manager has copies of all previous versions of the document.

To retrieve a former version of this policy from Q-Pulse, the Healthcare Governance Directorate should be contacted.

## **5 Standards/Key Performance Indicators**

The number of DATIX should not increase beyond the standard background rate.

## **6 Training**

Training on, and the practice of, accurate labelling of specimens and samples is delivered and supported organisationally through a range of methods/processes linked to clinical interventions, both medical and non-medical.

## **7 Trust Associated Documentation**

- Trust Identification of Patient's Policy.
- Trust Blood and Blood Component Policy

## **8 External References**

- Medical Laboratories- Requirements for quality and competence (ISO 15189:2012)
- Patient Sample and Request Form Identification Criteria, Council of the Institute of Biomedical Science (IBMS 2016)
- Provision of key clinical information on laboratory specimen request forms, Health and Safety Executive – Safety Notice: HID 5-2011
- NHSLA Risk Management Standards 5.6& 5.7 [Click Here](#)

MHRA was originally set up to monitor drug manufacture and evaluation (inc. trials). MHRA used the documented principles of GLP and GMP to monitor and audit performance in these areas. When the Blood Safety and Quality Regulations (1995) became law, MHRA was given the role monitoring compliance in blood transfusion establishments and continued to use these references for auditing purposes here.

- Blood Safety and Quality Regulations 2005 [Click Here](#)
- GLP [Click Here](#)
- GMP ISBN 978-85369-7190

## 9 Process for Monitoring Compliance and Effectiveness

In order to fully monitor compliance with this policy and ensure effective review, the policy will be monitored as follows:-

Minimum requirement to be monitored	Process for monitoring	Responsible Individual/ committee/ group	Frequency of monitoring	Responsible individual/ committee/ group for review of results	Responsible individual/ committee/ group for developing an action plan	Responsible individual/ committee/ group for monitoring of action plan
a. <i>Samples are unequivocally traceable, by request and labelling to an identified patient or site.</i>	All samples entering specimen reception are checked by reception staff. An AIR is submitted for any errors found.	All members of staff in Laboratory Medicine working in reception.	Constant	Quality Manager Directorate Management Team Clinical Governance Group	Quality Manager Directorate Management Team Clinical Governance Group	Quality Manager Directorate Management Team Clinical Governance Group
b. <i>Laboratory developed and documented criteria for acceptance or rejection of samples are applied</i>	Missing or erroneous information on the request can be picked up at any stage in the analytical process. An AIR is submitted for any instances found	All members of staff in Laboratory Medicine	Constant	Quality Manager Directorate Management Team Clinical Governance Group	Quality Manager Directorate Management Team Clinical Governance Group	Quality Manager Directorate Management Team Clinical Governance Group

## Appendix 2      Dissemination and Implementation Plan

Title of document:	Policy for Completing Request Forms and Labelling Samples
Date finalised:	
Previous document in use?	Yes
Dissemination lead	Elizabeth Fox
Implementation lead	Elizabeth Fox
Which Strategy does it relate to?	Quality & Safety

### Dissemination Plan

Method(s) of dissemination	Publish on Staff Room and Trust Website, A-Z of services, Laboratory Medicine
Who will do this	Policy Manager
Date of dissemination	On approval of document
Format (i.e. paper or electronic)	Electronic

### Implementation Plan

Name of individual with responsibility for operational implementation, monitoring etc	Quality Manager – Laboratory Medicine
Brief description of evidence to be collated to demonstrate compliance	The number of DATIX should not increase beyond the standard background rate.